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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,906	10/29/2003	Albert K. Chin	23488-07961	9199
758	7590	10/06/2005		
FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			EXAMINER BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,906

Applicant(s)

CHIN ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-28 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-13 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 3-4 and 14-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date All.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2) The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

- 3) This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 4) Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (US 4,235,246) in view of Bowers (US 3,920,024). Weiss discloses the

applicant's basic inventive method including temporarily positioning an electrode at locations about the heart, which in this case involves the physician probing the heart wall with a stimulating needle probe 38 (Col. 5, line 5). By probing at different locations, the physician is analyzing the patient threshold and then affixing a cardiac electrode at the desired stimulating location based on the analysis (Col. 5, line 6).

Weiss discloses that determining the patient threshold and the best location to attach a cardiac electrode is done using "conventional threshold testing means" (Col. 7, line 59), but goes into no detail as to what these means are. Attention is directed to the secondary reference of Bowers, which describes a method for threshold testing of the heart. Bowers discloses supplying stimulation signals, of which pacing signals could be included, to the heart and then sensing physiological activity of the heart in response to these signals in order to determine the threshold level of the heart (Col. 17 and 18, claim 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Bowers to modify the method of Weiss by using a threshold testing system involving delivering both stimulation signals and sensing signals from the heart in order to locate the preferred position on the heart to attach an electrode.

- 5) Claims 2, 5-6, 8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (US 4,235,246) in view of Cohen (US 5,336,252). Weiss, as modified above, discloses the applicant's basic inventive concept including screwing a helical distal end 50 (as shown in figure 5b) of the cardiac electrode through the use of a screwdriver apparatus rotated by the physician outside of the

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body (Col. 6, line 40). Weiss does not disclose using a suction attachment when temporarily positioning the electrode as well as when fixing the electrode at the preferred location on the epicardium. Attention is directed to the secondary reference of Cohen, which describes the use of a suction cup at the end of a catheter that secures the cup to the heart in order to allow for electrodes to be attached (Col. 11, line 22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Weiss by adding a suction attachment to secure to the heart in order to provide safe and reversible attachment to the heart (Col. 11, line 13).

6) Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (US 4,235,246) in view of Cohen (US 5,336,252) and further in view of Routh (US 6,096,064). Weiss, as modified above, discloses the applicant's basic inventive concept except for monitoring the mitral valve regurgitation in response to applied pacing signals. However, Routh discloses that one of the purposes of cardiac pacing is to reduce the regurgitation of blood through the mitral valve (Col. 2, line 42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Weiss by monitoring mitral valve regurgitation in order to find the location on the heart which best reduces the amount of blood regurgitated through the mitral valve.

7) Claims 12, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,336,252) in view of Flom et al (US 5,904,711). Cohen discloses the applicant's basic inventive concept including a guide channel in the form of a

semi-rigid sheath 136 which is axially slid relative to the suction port along the guide wire (Col. 14, line 26). The guide channel houses a defibrillation lead 140, which is advanced through the sheath from the proximal end to the distal end (Col. 14, lines 25-32), allowing the distal end of the lead to contact the heart, as shown in figure 21.

Cohen also discloses a suction cup positioned on the distal end of the instrument, which attaches to the surface of the pericardium (Col. 5, lines 6-9). The suction cup is connected to a suction channel, which is connected to a vacuum pump as a source of suction (Col. 5, lines 5-9). Cohen also shows in Figure 24, that the guide channel released the cardiac lead, leaving it anchored to the heart, as the guide channel was reconfigured from a position inside the body to a position outside of the body. Cohen does not disclose, however, that an electrode is disposed on a surface of the suction port that contacts the heart, and that this electrode is connected to a conductor extending between the distal and proximal ends of the instrument.

Attention is directed to the secondary reference of Flom, which discloses a conductive surface 186 that is connected to elastomeric member 184, which acts as a suction port as a vacuum source draws air through a suction lumen, thus drawing the elastomeric member, and the conductive surface, into contact with the heart due to the pressure change (Col. 15, lines 10-20). Also, the conductive surface is inherently connected to a conductor extending between the distal and proximal ends of the instrument in order to energize the conductor, as shown in figure 9.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the instrument of Cohen by adding an electrode to

the surface of the suction port in order to improve the electrical contact between the electrode and the heart to increase current flow between the two (Col. 15, line 17)

- 8) Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,336,252) in view of Flom et al (US 5,904,711) and further in view of Sommer et al. (US 6,132,456). Cohen, as modified above, discloses the applicant's basic inventive concept, including having a endoscopic cannula 84 and a suction attachment 92 supported by the cannula (as shown in figure 14) for contacting the heart under the visualization of a flexile endoscope 98 (Col. 12, line 2). Cohen does not disclose, however, a support guide channel which is selectively configurable as a closed channel or as an open channel. Attention is directed to the reference of Sommer, which shows a tubular channel 72 which holds a lead body 12 while insertion breach 75 is in a closed position, as shown in figure 8. However, channel 72 can be reconfigured by stretching open the breach to allow the lead body to be moved into and out of the channel (Col. 11, line 65), as shown in figure 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the instrument of Cohen to have a reconfigurable support channel for a lead in order to allow the lead to be released and left behind when the channel is removed.

Allowable Subject Matter

- 9) Claims 3-4 and 14-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


10) Claims 19-28 are allowable over the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

Eric D. Bertram
Examiner
Art Unit 3762

EDB